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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/603,665	06/23/2000	Caroline Barry	G-067US03REG	8150

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EXAMINER

BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
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1631

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

A

Office Action Summary	Application No.	Applicant(s)	
	09/603,665	BARRY ET AL.	
	Examiner	Art Unit	
	Michael Borin	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 133-146 is/are pending in the application.
- 4a) Of the above claim(s) 139-146 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 133-138 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

Amendment filed 01/24/2007 is acknowledged. Claims 133-146 are pending. Claim 134 is amended. Claims 139-146 remain withdrawn from further consideration.

Claim Rejections - 35 USC § 112, first paragraph.

Rejection of claims 133,134,136-138 are rejected under 35 U.S.C. 112, first paragraph (written description) is withdrawn in view of applicant's argument.

Claim Rejections - 35 USC § 112, second paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 134 is rejected under 35 U.S.C. 112, second paragraph, as being vague and indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is amended to recite that the protein "is associated" with prostate cancer (compared to previously rejected language that the protein plays "a role in the development of prostate cancer"). Similarly to the previous claim language, it is not clear in what manner the protein "is associated" with prostate cancer.

Claim Rejections - 35 U.S.C. § 101/ 112-1

The following is a quotation of the 35 U.S.C. § 101:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 133-138 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility.

The claims are drawn to polypeptide of SEQ ID No. 5 or fragment thereof containing residues 1-1629. Specification addresses the polypeptides as BAP28 proteins, i.e., proteins encoded by BAP 28 gene. Specification discloses that the polypeptide SEQ ID No. 5 is encoded by cDNAs SEQ ID Nos. 2 or 3 (p. 6), describes methods of making the polypeptides (p. 48-52) and how to screen for substances that interact with the polypeptides (p. 108-109). However, there is no disclosure on utility of the claimed polypeptides, neither the full-length, nor the fragment. With regard to information presented in the Figures, while Fig. 3 shows alignment to other known polypeptides, and Figures 7-12 demonstrate results of haplotype association analysis, they do not demonstrate the use of the polypeptide of SEQ ID No. 5 itself. Even though claim 134 addresses some role that polypeptide SEQ ID No. 5 plays in

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development of prostate cancer, such role is neither defined nor demonstrated in the specification. Thus, utility of the polypeptide depends on the activity/function of the polypeptide which is yet to be discovered by further research. The apparent need for such research clearly indicates that the polypeptide is not disclosed as to a currently available or substantial utility. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case none of the proteins that are to be produced as final products resulting from processes

The examiner does not find an adequate nexus between the evidence of record and the asserted properties of the claimed subject matter. Applicant should explicitly identify a specific, substantial, and credible utility for the claimed invention and establish a probative relation between any evidence of record and the originally disclosed properties of the claimed invention.

Response to arguments

Applicant submits that BAP28 polypeptide “has a number of phosphorylation sites and contains motif to be involved in protein-protein interaction”. This generic statement which is attributable to almost any protein does not translate into a specific and substantial utility of the claimed protein. Applicant then argues that BAP28 protein “should have” ability to interact with BRCA1. This asserted and not demonstrated utility is not substantial, as it will require further research to identify significance of such interaction. Furthermore, applicant discusses presence of bi-allelic markers within the

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gene encoding BAP28 protein. Discussion of structural characteristics of a gene is unrelated to demonstration of the utility of the protein. Finally, the fact of protein expression in cells demonstrated in post-filing date Internet reference <http://www.expasy.org/swiss-2dpage/protein/ac=Q9H583> - and much less the presumed expectation of the protein expression, alleged by applicant - is not demonstration of a practical utility of the protein.

Claims 133-138 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by a substantial or a well-established utility for the reasons set forth above, one skilled in the art would not know how to make and/or use the claimed invention.

Conclusion.

No claims are allowed

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571)272-0735 . The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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A handwritten signature in black ink, appearing to read "Michael Borin", with a long, sweeping horizontal stroke extending to the right.

Michael Borin, Ph.D.

Primary Examiner

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mlb